

FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark Office

Atty Docket No.  
P1795R1

Serial No.  
09/738,540

**LIST OF DISCLOSURES CITED BY APPLICANT**

(Use several sheets if necessary)

Applicant  
Lee et al.

Filing Date  
14 Dec 2000

Group  
1644

**U.S. PATENT DOCUMENTS**

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	1	5,336,603	09.08.94	Capon et al.			
	2	5,514,582	07.05.96	Capon et al.			
	3	5,565,335	15.10.96	Capon et al.			
	4	5,594,106	14.01.97	Black et al.			
	5	5,605,690	25.02.97	Jacobs et al.			
	6	5,629,285	13.05.97	Black et al.			
	7	5,654,407	05.08.97	Boyle et al.			
	8	5,656,272	12.08.97	Le et al.			
	9	5,698,195	16.12.97	Le et al.			
	10	5,712,155	27.01.98	Smith et al.			
	11	5,795,967	18.08.98	Aggarwal et al.			
	12	5,919,452	06.07.99	Le et al.			
	13	5,945,397	31.08.99	Smith et al.			
	14	5,981,701	09.11.99	Wallach et al.			
	15	5,985,620	16.11.99	Sioud			
	16	5,994,510	30.11.99	Adair et al.			
	17	5,997,867	07.12.99	Waldmann et al.			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No	
	18	212,489 B1	30.11.94	EPO				
	19	218,868 A3	22.04.87	EPO				
	20	288,088 B1	09.03.94	EPO				
	21	308,378 B1	30.11.94	EPO				
	22	398,327 B1	15.03.95	EPO				
	23	412,486 B1	30.11.94	EPO				
	24	433,900 B1	20.09.95	EPO				
	25	526,905 A2	10.02.93	EPO				
	26	WO 00/56363	28.09.00	PCT				
	27	WO 92/07076	30.04.92	PCT				
	28	WO 92/11383	09.07.92	PCT				
	29	WO 92/13095	06.08.92	PCT				
	30	WO 92/16553	01.10.92	PCT				
	31	WO 97/29131	14.08.97	PCT				
	32	WO 98/22137	28.05.98	PCT				
	33	WO 98/23761	04.06.98	PCT				

Examiner *Mohamed Herdad*

Date Considered  
*7/3/02*

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark Office

Atty Docket No.

P1795R1

Serial No.

09/738,540

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Lee et al.

Filing Date

14 Dec 2000

Group

1644

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

- 34 Aderka et al., "The possible role for tumor necrosis factor (TNF) and its natural inhibitors, the soluble-TNF receptors, in autoimmune diseases" Isrl. J. Med. Sci. 20:126-130 (1993)
- 35 Bringman and Aggarwal, "Monoclonal Antibodies to Human Tumor Necrosis Factor Alpha and Beta: Application for Affinity Purification, Immunoassays, and as Structural Probes" Hybridoma 6:489-507 (1987)
- 36 Buchan et al., "Interleukin 1 and tumour necrosis factor mRNA expression in rheumatoid arthritis: prolonged production of IL-1 $\alpha$ " Clin. Exp. Immunol. 73:449-455 (1988)
- 37 Campana et al., "Human leukocyte function-associated antigens on lympho-hemopoietic precursor cells" European Journal of Immunology 16(5):537-542 (May 1986)
- 38 Chen et al., "Chondrocyte transplantation and experimental treatment options for articular cartilage defects" American Journal of Orthopedics 26(6):396-406 (1997)
- 39 Desroches et al., "Regulation and Functional Involvement of Distinct Determinants of Leucocyte Function-Associated Antigen 1 (LFA-1) in T-Cell Activation In Vitro" Scand. J. Immunol. 33:277-286 (1991)
- 40 Dustin and Springer, "Lymphocyte function-associated antigen-1 (LFA-1) interaction with intercellular adhesion molecule 1 (ICAM-1) is one of at least three mechanisms for lymphocyte adhesion to cultured endothelial cells" Journal of Cell Biology 107(1):321-331 (Jul 1988)
- 41 Engelmann et al., "A Tumor Necrosis Factor-binding Protein Purified to Homogeneity from Human Urine, Protects Cells from Tumor Necrosis Factor Toxicity" Journal of Biological Chemistry 264:11974-11980 (1989)
- 42 Engelmann et al., "Two Tumor Necrosis Factor Binding Proteins Purified from Human Urine" Journal of Biological Chemistry 265(3):1531-1536 (1990)
- 43 Exley et al., "Monoclonal antibody to TNF in severe septic shock" Lancet 335:1275-1276 (1990)
- 44 Pekete et al., "Involvement of Lymphocyte Function-Associated Antigen-1 (LFA-1) But Not ICAM-1 in a Radioactive Leukocyte Cell-Mediated Immunity (LA-CMI) Assay" J. Clin. Lab. Immunol. 31:145-149 (1990)
- 45 Feldmann, M., "What is the Mechanism of Action of Anti-Tumor Necrosis Factor  $\alpha$  Antibody in Rheumatoid Arthritis?" Int Arch Allergy Immunol 111:362-365 (1996)
- 46 Fendly et al., "Murine Monoclonal Antibodies Defining Neutralizing Epitopes on Tumor Necrosis Factor" Hybridoma 6:359-369 (1987)
- 47 Fischer et al., "Role of the LFA-1 Molecule in Cellular Interactions Required For Antibody Production in Humans" The Journal of Immunology 136(9):3198-3203 (May 1, 1986)
- 48 Gao and Issekutz, "Mac-1 (CD11b/CD18) is the predominant  $\beta_2$  (CD18) integrin mediating human neutrophil migration through synovial and dermal fibroblast barriers" Immunology 88:463-470 (1996)
- 49 Herve et al., "Monoclonal Anti  $\alpha$  Antibody for the Treatment of Severe Acute GVHD in Humans" Lymphoma Res. (Abstract No. 3.25) 9:391 (1990)
- 50 Hildreth et al., "A Human Lymphocyte-associated Antigen Involved in Cell-mediated Lympholysis" European Journal of Immunology 13:202-208 (1983)
- 51 Hirai et al., "Production and characterization of monoclonal antibodies to human tumor necrosis factor" J. Immunol. Meth. 96:57-62 (1987)
- 52 Howard et al., "Soluble Tumor Necrosis Factor Receptor: Inhibition of Human Immunodeficiency Virus Activation" Proc. Natl. Acad. Sci. USA 90:2335-2339 (1993)

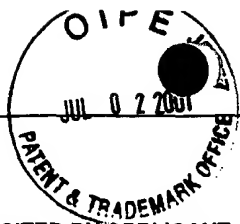
Examiner

Maher Haddad

Date Considered

7/3/02

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark Office

Atty Docket No.

P1795R1

Serial No.

09/738,540

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Lee et al.

Filing Date

14 Dec 2000

Group

1644

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

- 53 Isaacs et al., "Humanized anti-CD4 monoclonal antibody therapy of autoimmune and inflammatory disease" Clinical & Experimental Immunology 110(2):158-166 (Nov 1997)
- 54 Ishikawa et al., "The Role of Adhesion Molecules in Synovial Pannus Formation in Rheumatoid Arthritis" Clinical Orthopaedics and Related Research 300:297-303 (1994)
- 55 Joosten et al., "IL-1 $\alpha$  Blockade Prevents Cartilage and Bone Destruction in Murine Type II Collagen-Induced Arthritis, Whereas TNF- $\alpha$  Blockade Only Ameliorates Joint Inflammation" Journal of Immunology 163:5049-5055 (1999)
- 56 Krewer, J.M., "Combination therapy with biological agents in rheumatoid arthritis: perils and promise" Arthritis and Rheumatism 41(9):1548-1551 (1999)
- 57 Krensky et al., "The Functional Significance, Distribution, and Structure of LFA-1, LFA-2, and LFA-3: Cell Surface Antigens Associated with CTL-Target Interactions" The Journal of Immunology 131(2):611-616 (August 1983)
- 58 Kuypers and Boos, "Leukocyte Membrane Adhesion Proteins LFA-1, CR3 and p150,95: A Review of Functional and Regulatory Aspects" Res. Immunol. 140:461-486 (1989)
- 59 Liang et al., "Production and Characterization of monoclonal antibodies against recombinant human tumor necrosis factor/cachectin" Biochem. & Biophys. Res. Comm. 137:847-854 (1986)
- 60 Loetscher et al., "Molecular Cloning and Expression of the Human 55 kd Tumor Necrosis Factor Receptor" Cell 61:351-359 (1990)
- 61 Lovell et al., "Safety and Efficacy of Tumor Necrosis Factor Receptor P75 FC Fusion Protein" Arthritis and Rheumatism (Abstract No. 584) 41(9):S130 (1998)
- 62 Maini et al., "Therapeutic efficacy of multiple intravenous infusions of anti-tumor necrosis factor  $\alpha$  monoclonal antibody combined with low-dose weekly methotrexate in rheumatoid arthritis" Arthritis and Rheumatism 41(9):1552-1563 (1998)
- 63 Meager et al., "Preparation and Characterization of Monoclonal Antibodies Directed Against Antigenic Determinants of Recombinant Human Tumor Necrosis Factor (rTNF)" Hybridoma 6:305-311 (1987)
- 64 Mohler et al., "Soluble tumor necrosis factor (TNF) receptors are effective therapeutic agents in lethal endotoxemia and function simultaneously as both TNF carriers and TNF antagonists" Journal of Immunology 151(3):1548-1561 (Aug 1, 1993)
- 65 Mohler et al., "Monoclonal Antibodies to Human Tumor Necrosis Factor  $\alpha$ : In Vitro and In Vivo, Application" Cytokine 3:162-169 (1990)
- 66 Moreland et al., "Etanercept Therapy in Rheumatoid Arthritis: A Randomized, Controlled Trial" Annals of Internal Medicine 130:478-486 (1999)
- 67 Moreland et al., "Longterm Treatment of DMARD Failing Rheumatoid Arthritis Patients with TNF Receptor P75 FC Fusion Protein" J. Invest. Med. (abstract only) 46:229A (1998)
- 68 Nakatsuka et al., "Rheumatoid Synovial Fibroblasts Are Stimulated by the Cellular Adhesion to T Cells Through Lymphocyte Function Associated Antigen-1/Intercellular Adhesion Molecule-1" J. Rheumatology 24:458-464 (1997)
- 69 Nishimura et al., "The role of lymphokine-activated cell-associated antigen. III. Inhibition of T-cell activation by monoclonal killer-blocking antibody" Cellular Immunology 107(1):32-39 (Jun 1987)
- 70 Nopar et al., "Soluble forms of tumor necrosis factor receptors (TNF Rs). The cDNA for the type I TNF-R, cloned using amino acid sequence data of its soluble form, encodes both the cell surface and a soluble form of the receptor" EMBO Journal 9:3269-3278 (1990)
- 71 Peppel et al., "A Tumor Necrosis Factor (TNF) Receptor IgG Heavy Chain Chimeric Protein as a Bivalent Antagonist of TNF Activity" Journal of Experimental Medicine 174:1483-1489 (1991)
- 72 Sanchez-Madrid et al., "Mapping of antigenic and functional epitopes on the  $\alpha$  and  $\beta$  subunits of two related mouse glycoproteins involved in cell interactions, LFA-1 and MAC-1" Journal of Experimental Medicine 158(2):586-602 (Aug 1, 1983)

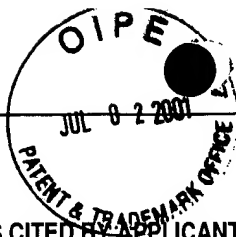
Examiner

Maher Herddad

Date Considered

7/3/02

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark Office

Atty Docket No.

P1795R1

Serial No.

09/738,540

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Lee et al.

Filing Date

14 Dec 2000

Group

1644

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

- |    |  |
|----|--|
| 73 | <del>Schall et al., "Molecular Cloning and Expression of a Receptor for Human Tumor Necrosis Factor" Cell 61:361-370 (1990)</del>  |
| 74 | <del>Seckinger et al., "A Human Inhibitor of Tumor Necrosis Factor <math>\alpha</math>" Journal of Experimental Medicine 167:1511-1516 (1988)</del>  |
| 75 | <del>Spencer-Green, G., "Etanercept (Enbrel): update on therapeutic use" Ann. Rheum. Dis. 59:146-149 (2000)</del>  |
| 76 | <del>Springer et al., "LFA-1 and Lys 2,3, molecules associated with T lymphocyte-mediated killing, and Mac-1, an LFA-1 homologue associated with complement receptor function" Immunol. Rev. 68:171-195 (1982)</del>                             |
| 77 | <del>Springer et al., "The lymphocyte function-associated LFA-1, CD2, and LFA-3 molecules: cell adhesion receptors of the immune system" Annual Review of Immunology 5:223-252 (1987)</del>  |
| 78 | <del>Strand et al., "Biological Agents for the Treatment of Rheumatoid Arthritis" Clinical Immunology and the Rheumatologist 22(1):117-132 (1996)</del>  |
| 79 | <del>Taylor et al., "The expression of CD18 is increased on Trisomy 21 (Down syndrome) lymphoblastoid cells" Clinical &amp; Experimental Immunology 71(2):324-328 (Feb 1988)</del>   |
| 80 | <del>Ulrich et al., "Short Communication: Intratracheal Administration of Endotoxin and Cytokines IV: The Soluble Tumor Necrosis Factor Receptor Type I Inhibits Acute Inflammation" American Journal of Pathology 142(5):1335-1338 (1993)</del> |
| 81 | <del>Weinblatt et al., "A Trial of Etanercept, a Recombinant Tumor Necrosis Factor Receptor: Fc Fusion Protein, in Patients with Rheumatoid Arthritis Receiving Methotrexate" New England J. of Medicine 340(4):253-259 (1999)</del>             |
| 82 | <del>Williams et al., "Anti-tumor necrosis factor ameliorates joint disease in murine collagen-induced arthritis" Proc. Natl. Acad. Sci. USA 89:9784-9788 (1992)</del>   |
| 83 | <del>Williams et al., "Synergy between anti-CD4 and anti-tumor necrosis factor in the amelioration of, established collagen-induced arthritis" Proc. Natl. Acad. Sci. USA 91:2762-2766 (1994)</del>  |
| 84 | <del>Williams, R.O., "Combination therapy in mice: what can we learn that may be useful for understanding rheumatoid arthritis" Springer Seminars in Immunopathology 20:165-180 (1998)</del>   |
| 85 | <del>Woolley et al., "Influence of a Recombinant Human Soluble Tumor Necrosis Factor Receptor FC Fusion Protein on Type II Collagen-Induced Arthritis in Mice" The Journal of Immunology 151(11):6602-6607 (1993)</del>                          |
|    |  |
|    |  |
|    |  |
|    |  |
|    |  |
|    |  |
|    |  |
|    |  |
|    |  |
|    |  |

Examiner

Maha Haddad

Date Considered

7/3/02

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.